REMARKS

Applicant wishes to thank the Examiner for the courteous personal interview and for the helpful comments provided therein. Currently, Claims 1-20 are pending in the application. No amendments have been made and Applicant respectfully requests examination of Claims 1-20 on the merits.

Claim Rejections under §102(e)

In an office action dated May 28, 2004, the Examiner rejected Claims 1-20 under section 102(e) "as being anticipated by either Conkling et al (US. Pat. App. Pub. 2003/0118997) or Conkling et al (US. Pat. App. Pub. 2004/0103454)."

Specifically, the examiner stated:

> The applied reference has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.
>
> Either reference discloses all that is recited in the claims (see entire document. Note: Both nicotine and nitrosamine values can be 0 ppm or 0 ppb).

In response, Applicant submits, pursuant to 37 C.F.R. 1.132, the Declarations of Dr. Mark Conkling and Dr. Yan Li. Applicant submits that the Declarations establish that to the extent the cited references (U.S. Pat. App. Pub. 2003/0118997 and U.S. Pat App. Pub. 2004/0103454) relate to Application No. 10/729,121, they are not the work of another and they therefore are not prior art under 35 U.S.C. § 102(e) with respect to Application No. 10/729,121. Both Dr. Conkling and Dr. Li attest to the fact that Dr. Conkling is the sole inventor of the claimed technology. For this reason applicant respectfully requests withdrawal of the rejection of claims 1-20 of the present application based upon U.S. Pat. App. Pub. 2003/0118997 and U.S. Pat App. Pub. 2004/0103454.

Claim Rejections under §103(a)

The examiner also rejected claims 1-20 under 35 U.S.C. 103(a) "as obvious over WO 98/56923." Specifically, the examiner stated:

> WO 98/56923 discloses transgenic tobacco that is free of nicotine and is suitable for use in any tobacco product. While there may be no articulation that the tobacco is cured, this would have been an obvious property since "curing" tobacco is a conventional process in the production of tobacco products. Further, while there may [sic] specific articulation of the nitrosamine content, it follows that since the tobacco of WO 98/56923 contains no nicotine, the same can obviously be said of the nitrosamine content, as well, since by removing the nicotine from the tobacco, one effectively removes the alkaloid substrate for TSNA formation (see 2004/0103454).
>
> Regarding claim 20, while there may be no specific disclosure of Burley tobacco in the invention of WO 98/56923, it follows that one having ordinary skill in the art would have opted to use this type of tobacco since it is conventionally used in the production of many tobacco products.

Applicant respectfully disagrees and traverses the rejection. Under 35 U.S.C. §103(a), an invention that is not identically disclosed in the prior art may still be unpatentable "if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains." In determining obviousness, a court must (1) determine the scope and content of the prior art, (2) determine the differences between the prior art and the claims, (3) ascertain the level of ordinary skill in the art, and (4) evaluate any objective evidence of nonobviousness. *Graham v. John Deere Co.*, 383 U.S. 1 (1966). Additionally, the analysis must focus on the state of knowledge at the time the invention was made; the analysis must not involve the use of hindsight. *In re Raynes*, 7 F.3d 1037 (Fed. Cir. 1993); *see also W.L. Gore & Assocs., Inc. v. Garlock, Inc.*, 721 F.2d 1540, 1550 (Fed. Cir. 1983).

Applicant presents the following arguments to traverse the rejection under section 103. First, WO 98/56923 contains no discussion of nitrosamine content and no discussion of specific levels of reduction of nicotine. WO 98/56923 describes a general technique that can be used to

reduce nicotine levels in tobacco. The application does not describe the amount of nicotine reduction that can be obtained using the technique and makes no mention of nitrosamines. More specifically, the cited reference does not teach that the low levels of nicotine and/or nitrosamine content claimed in the present application was achieved or could be achieved. In fact, Dr. Conkling's achievement of the specific, low levels of nitrosamine content claimed in the present application was unexpected. Indeed, WO 98/56923 discloses that the extent of antisense inhibition of the QPTase gene in tobacco plants is highly variable and unpredictable. Thus, one of ordinary skill in the art having only WO 98/56923 would not recognize that one could achieve the low levels of nitrosamine content claimed in the present invention. Second, the examiner cited U.S. Pat App. Pub. 2004/0103454 for the proposition that lowered nicotine levels correspond to lower nitrosamine content. As argued above, however, that reference is not prior art under 102(e) because it is not the work of another. In addition, that reference is not otherwise prior art because it was published (on May 27, 2004) after the filing date of the present application (Dec. 4, 2003). Therefore, U.S. Pat. App. Pub. 2004/0103454 cannot form the basis for a rejection under section 103.

Accordingly, applicant submits that WO 98/56923 only teaches that antisense inhibition can be used to decrease nicotine levels in tobacco. The reference does not include data showing an amount of nicotine reduction sufficient to obtain the claimed nitrosamine levels nor does the reference mention at all that nitrosamine reduction can be achieved. Antisense inhibition is unpredictable and it was quite unexpected to obtain the reduction of nicotine to a level that allows for a collective content of TSNAs at 0.5 μg/g or less in the cured tobacco. The claimed invention is not obvious because the cited reference does not teach or suggest a genetically modified, cured tobacco comprising a reduced amount of nicotine and a collective content of TSNAs of less than about 0.5 μg/g. A general teaching of antisense inhibition of the QPTase gene in tobacco cannot make obvious claims to a reduced nicotine tobacco comprising the claimed levels of nitrosamines.

CONCLUSION

In view of the arguments presented herein, Applicant respectfully submits that the claims are in condition for allowance and such action is earnestly requested. If, however, any unresolved issues remain, Applicant requests that the Examiner contact Applicant's attorney Eric

S. Furman Ph.D., J.D. at 619-687-8643 (direct dial) so that such matters can be resolved over the telephone.

No further fees are seen as being necessary for the filing of this paper, however, if a fee is required, please charge any additional fees, including any fees for additional extension of time, or credit overpayment to Deposit Account No. 11-1410.

Respectfully submitted,

KNOBBE, MARTENS, OLSON & BEAR, LLP

Dated: September 21, 2004

By: _____

Eric S. Furman, Ph.D.
Registration No. 45,664
Attorney of Record
Customer No. 20,995
(619) 235-8550

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